

part or the regulations in parts 305, 307, and 308 of this subchapter or that the applicant has not received approval of labeling and containers to be used at the establishment as required by the regulations in parts 316 and 317 of this subchapter. When inspection is refused for any reason, the applicant shall be informed of the action and the reasons therefor and afforded an opportunity to present his views.

(c) Inspection may also be refused in accordance with section 401 of the Act and the applicable rules of practice.

(d)(1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters in the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), to provide the Administrator with a certification as prescribed in said subsection that there is reasonable assurance that such activity will be conducted in a manner which will not violate the applicable water quality standards. No grant of inspection can be issued after April 3, 1970 (the date of enactment of the Water Quality Improvement Act), unless such certification has been obtained, or is waived because of failure or refusal of the State, interstate agency or the Secretary of the Interior to act on a request for certification within a reasonable period (which shall not exceed 1 year after receipt of such request).

(2) However, certification is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although certification for such facilities is required to be obtained within the 3-year period immediately following April 3, 1970. Failure to obtain such certification and meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date.

Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless

prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

(e) Inspection may be refused in accordance with humane slaughter and handling provisions of the Act (21 U.S.C. 603(b)) and the applicable rules of practice.

[35 FR 15558, Oct. 3, 1970, as amended at 41 FR 4889, Feb. 3, 1976; 44 FR 68813, Nov. 30, 1979; 62 FR 45024, Aug. 25, 1997]

§304.3 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, as required by §§417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with §417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with §417.4 of this chapter.

[61 FR 38864, July 25, 1996]

PART 305—OFFICIAL NUMBERS; INAUGURATION OF INSPECTION; WITHDRAWAL OF INSPECTION; REPORTS OF VIOLATION

Sec.

305.1 Official numbers; subsidiaries and tenants.

305.2 Separation of official establishments.

305.3 Sanitation and adequate facilities.

305.4 Inauguration of inspection.

305.5 Withdrawal of inspection; statement of policy.

305.6 Reports of violations.

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

§ 305.1

SOURCE: 35 FR 15559, Oct. 3, 1970, unless otherwise noted.

§ 305.1 Official numbers; subsidiaries and tenants.

(a) An official number shall be assigned to each establishment granted inspection. Such number shall be used to identify all inspected and passed products prepared in the establishment. More than one number shall not be assigned to an establishment.

(b) Two or more official establishments under the same ownership or control may be granted the same official number, provided a serial letter is added in each case to identify each establishment and the products thereof.

(c) When inspection has been granted to any applicant at an establishment, it shall not be granted to any other person at the same establishment. However, persons operating as separate entities in the same building or structure may operate separate establishments therein only under their own grant of inspection. All such persons operating separate establishments in the same building or structure shall be responsible for compliance with the Act and regulations in their own establishments, which shall include common areas, e.g., hallways, stairways, and elevators.

[35 FR 15559, Oct. 3, 1970, as amended at 40 FR 2576, Jan. 14, 1975]

§ 305.2 Separation of official establishments.

(a) Each official establishment shall be separate and distinct from any unofficial establishment except a poultry products processing establishment operated under Federal inspection under the Poultry Products Inspection Act or under State inspection.

(b) The slaughter or other preparation of products of horses, mules, or other equines required to be conducted under inspection pursuant to the regulations in this subchapter shall be done in establishments separate from any establishment in which cattle, sheep, swine, or goats are slaughtered or their products are prepared.

(c) Inspection shall not be inaugurated in any building, any part of which is used as living quarters, unless the part for which inspection is re-

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quested is separated from such quarters by floors, walls, and ceilings of solid concrete, brick, wood, or similar material, and the floors, walls, and ceilings are without openings that directly or indirectly communicate with any part of the building used as living quarters.

§ 305.3 Sanitation and adequate facilities.

Inspection shall not be inaugurated if an establishment is not in a sanitary condition nor unless the establishment agrees to maintain a sanitary condition and provides adequate facilities for conducting such inspection.

§ 305.4 Inauguration of inspection.

When inspection is granted, the circuit supervisor shall, at or prior to the inauguration of inspection, inform the operator of the establishment of the requirements of the regulations in this subchapter. If the establishment, at the time inspection is inaugurated, contains any product which has not theretofore been inspected, passed, and marked in compliance with the regulations in this subchapter, the identity of the same shall be maintained, and it shall not be distributed in commerce, or otherwise subject to the requirements of such regulations, or dealt with as inspected and passed under the regulations. The establishment shall adopt and enforce all necessary measures and shall comply with all such directions as the circuit supervisor may prescribe, for carrying out the purposes of this section.

§ 305.5 Withdrawal of inspection; statement of policy.

(a) The Administrator is authorized to withdraw inspection from an official establishment where the sanitary conditions are such that its products are rendered adulterated, or for failure of the operator to destroy condemned products as required by the Act and the regulations in this subchapter. Inspection may be withdrawn in accordance with section 401 of the Act and the applicable rules of practice.

(b) The assignment of inspectors may be temporarily suspended, in whole or in part, by the Administrator to the extent it is determined necessary to

avoid impairment of the effective conduct of the program when the operator of any official establishment or any subsidiary therein, or any officer, employee, or agent of any such operator or any subsidiary therein, acting within the scope of his office, employment, or agency, threatens to forcibly assault or forcibly assaults, intimidates, or interferes with any program employee in or on account of the performance of his official duties under the act, unless promptly upon the incident being brought by an authorized supervisor of the program employee to the attention of the operator of the establishment the operator (1) satisfactorily justifies the incident, (2) takes effective steps to prevent a recurrence, or (3) provides acceptable assurance that there will not be any recurrences. Such suspension shall remain in effect until one of such actions is taken by the operator: *Provided*, That upon request of the operator he shall be afforded an opportunity for an expedited hearing to show cause why the suspension should be terminated.

(c) Inspection service may be temporarily suspended, in whole or in part, at an official establishment, by the Administrator, to the extent that it is determined necessary to prevent inhumane slaughtering or handling in connection with slaughter of livestock as defined in §301.2(kk) (9 CFR 301.2(kk)). The Administrator shall notify the operator of an establishment orally or in writing, as promptly as circumstances permit, of such suspension and the reasons therefor. Such suspension shall remain in effect until the operator of the establishment takes effective steps to prevent a recurrence, or provides other satisfactory assurances that there will not be any recurrences. Upon request, the operator shall be afforded an opportunity for a hearing to show cause why the suspension should be terminated.

[38 FR 9794, Apr. 20, 1973, as amended at 44 FR 68813, Nov. 30, 1979; 53 FR 49848, Dec. 12, 1988]

§ 305.6 Reports of violations.

Program employees shall report, in a manner prescribed by the Administrator, all violations of the Act or regulations in this subchapter of which they have information.

PART 306—ASSIGNMENT AND AUTHORITIES OF PROGRAM EMPLOYEES

Sec.

306.1 Designation of circuit supervisor and assistants.

306.2 Program employees to have access to establishments.

306.3 Badge as identification of inspectors.

306.4 Assignment of Program employees where members of family employed; soliciting employment; procuring product from official establishments.

306.5 Appeals.

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15559, Oct. 3, 1970, unless otherwise noted.

§ 306.1 Designation of circuit supervisor and assistants.

The Administrator shall designate a circuit supervisor of the inspection in each circuit, and assign to said inspector such assistants as may be necessary.

§ 306.2 Program employees to have access to establishments.

For the purpose of any examination or inspection necessary to prevent the use in commerce of any adulterated product, Program employees shall have access at all times, by day or night, whether the establishment is operated or not, to every part of any official establishment to which they are assigned. Access to establishments is also authorized in accordance with section 202 of the Act and the regulations in part 320 of this subchapter.

§ 306.3 Badge as identification of inspectors.

Each inspector will be furnished with a numbered official badge, which he shall not allow to leave his possession, and which he shall wear in such manner and at such times as the Administrator may prescribe. This badge shall be sufficient identification to entitle him to admittance at all regular entrances and to all parts of the establishment and premises to which he is assigned.